

OSTOMY POUCH AND METHOD OF ASSEMBLY

BACKGROUND OF THE INVENTION

This invention relates to a method of assembling an ostomy pouch and, more particularly, to a method of assembling a mounting plate for an ostomy pouch and for attracting the plate to a plastic sheet which forms one side of an ostomy pouch.

Typical one-piece ostomy appliances include a mounting faceplate interposed between a convex disc and an ostomy pouch. The proximal convex face of the disc is covered with a hydrocolloid skin barrier to seal against the peristomal skin surfaces of the ostomate. The distal wall of the faceplate is secured to a proximal wall of the pouch about a stoma opening in the pouch either by an adhesive, ultrasonic sealing, or heat sealing. The proximal wall of the faceplate is adhered to the distal face of the convex disc by an adhesive. The faceplate extends beyond the periphery of the convex disc so that the adhesive coating on the proximal wall of the faceplate is adhered to the ostomate's skin to mount the ostomy appliance.

Even though the mounting adhesive is hypoallergenic, medical grade, pressure-sensitive adhesive that is permeable to gas and water vapor, many ostomates find that the repeated removal of adhesive faceplates is quite painful, and, in some cases, causes skin ulceration. Those ostomates prefer the appliance to be belt-mounted with only the hydrocolloid skin barrier in contact with the peristomal skin areas.

SUMMARY OF THE INVENTION

This invention provides an ostomy appliance which overcomes many of the prior art problems and provides a simplified

1 technique for making the appliance.

2 A method of assembly includes the steps of providing a
3 flexible plastic disc having a convex central body portion and
4 a surrounding annular rim. A first foam disc is provided. The
5 disc has first and second faces coated with a pressure-sensitive
6 adhesive and an outer diameter substantially corresponding to the
7 outer diameter of the plastic disc. A second foam disc having
8 a pressure-sensitive adhesive coating on one of its faces and
9 having an outer diameter greater than the outer diameter of the
10 plastic disc is provided. The other uncoated face of the second
11 foam disc is adhered to the first foam disc. An adhesive
12 hydrocolloid skin barrier disc having an outer diameter corre-
13 sponding to that of the second foam disc is adhered to the
14 adhesive face of the second disc. The second face of the first
15 foam disc is adhered to the plastic disc. Heat and pressure are
16 applied to the hydrocolloid disc in an annular zone surrounding
17 the convex body portion of the plastic disc to seal the first and
18 second foam disc assembly to the plastic disc, to mold the
19 hydrocolloid disc to the shape of the convex body portion, and
20 to form a mounting disc.

21 At least one mounting disc is placed on a plastic sheet
22 which will form the proximal wall of one or more ostomy pouches.
23 The proximal surface of the sheet may be covered with a cloth-
24 like porous material for the comfort of the wearer. The center
25 of each disc is die-cut to provide a stoma-receiving opening.
26 The sheet is provided with apertures having diameters generally
27 coinciding with the inside diameter of the annular rim of the
28 convex disc.

1 With a mounting disc positioned so that the annular rim of
2 the convex disc contacts an annular zone of the sheet surrounding
3 the aperture, heat is applied to the disc to fuse the sheet
4 thereto. Thereafter, the sheet and its attached mounting discs
5 are placed on another sheet which will form the distal wall of
6 the ostomy pouch or pouches. Each pouch is then die-cut to shape
7 and the pouch perimeter is heat-sealed.

8 BRIEF DESCRIPTION OF THE DRAWINGS

9 Fig. 1 is a proximal elevational view of an ostomy appliance
10 according to this invention;

11 Fig. 2 is a cross-sectional view, the plane of the section
12 being indicated by the line 2-2 in Fig. 1;

13 Fig. 3 is an exploded view of a mounting disc according to
14 this invention; and

15 Fig. 4 is a plan view of the mounting discs applied to a
16 plastic sheet.

17 DETAILED DESCRIPTION OF THE INVENTION

18 Referring now to the drawings, and particularly to Figs. 1-
19 3, there is illustrated an ostomy appliance assembly 10 according
20 to this invention. The assembly 10 includes a mounting disc 12,
21 adapted to be attached to a fastening belt (not shown) of an
22 ostomate, and an ostomy pouch 14.

23 The mounting disc 12 includes a flexible plastic disc 16
24 having a convex central body portion 18 and a surrounding annular
25 rim 20. The disc may be molded from a copolymer of ethylene and
26 vinyl acetate (EVA). The EVA copolymer may be "ELVAX"® 450,
27 produced by E.I. DuPont de Nemours, Inc., Wilmington, Delaware.
28 The disc 16 is provided with diametrically opposed and radially

1 extending belt mounting loops 22 at its periphery.

2 A first soft resilient thermoplastic foam disc 24 covers the
3 flexible plastic disc 16. The foam disc 24 has pressure-
4 sensitive adhesive layers 26 and 28 on each of its faces and one
5 face is attached to the plastic disc 16. The foam disc 24, when
6 applied to the disc 16, has an outer diameter substantially
7 corresponding to the outer diameter of the disc 16.

8 ^{sub} A1 A second soft, resilient thermoplastic foam disc 30 covers
9 the first foam disc 24. The foam disc 30 has a pressure-
10 sensitive adhesive layer 32 on one face, and the other face of
11 the disc 24 is adhesively attached to the adhesive layer 28 of
12 the first foam disc 24 so that the pressure-sensitive layer is
13 exposed. The foam disc 30 has an outer diameter greater than the
14 outer diameters of the first foam disc 24 and the disc 16. The
15 mating loops 22 do not extend beyond the diameter of the second
16 foam disc 30 so that the skin of the ostomate is protected from
17 belt hooks passing through the loops 22.

18 An adhesive hydrocolloid skin barrier disc 34 having an
19 outer diameter corresponding to that of the second foam disc 30
20 is placed on the adhesive layer 32 of the second foam disc 30.
21 Preferably the exposed surface of the disc 34 is covered by a
22 thin release film 36 which is removed just prior to use. Heat
23 and pressure are applied to an annular zone z (Fig. 2) to seal
24 the discs and to smooth the foam and hydrocolloid discs over the
25 convex central body portion 18 of the plastic disc 16.

26 The adhesive skin barrier disc 34 is pliable and has both
27 dry and wet tack. Suitable materials are Karaya-glycerine
28 formulations or mixtures of polyacrylamide resins and other

1 polyols and mixtures of elastomers and hydrocolloids. A stoma
2 inlet portal 38 is provided at the center of the assembly, as
3 illustrated in Fig. 2.

4 The first and second foam discs 24 and 30, the hydrocolloid
5 skin barrier disc 34, and the plastic disc 16 are assembled in
6 the following manner. For ease of handling during the assembly
7 operation, the pressure-sensitive adhesive layers 26 and 28 of
8 the first foam disc 24 are respectively covered by protective
9 liners 40 and 42, and the adhesive layer 32 of the foam disc 30
10 is covered by a protective liner 44. The release liner 42 is
11 stripped from the adhesive layer 28 and the disc 24 is adhered
12 concentrically to the foam disc 30. To aid in this operation,
13 pilot apertures 46 and 48 are respectively provided at the
14 centers of the discs 24 and 30.

15 *Sub* After the discs 24 and 30 are assembled, the liner 44 is
16 *As* stripped from the adhesive layer 32 of the disc 30 and the
17 adhesive layer 32 of the disc 30 is applied concentrically to one
18 face 50 of the hydrocolloid disc 34. To aid in this operation,
19 a pilot aperture 52 is provided at the center of the disc 34.

20 After the discs 24, 30 and 34 are assembled, the liner 40
21 is stripped from the adhesive layer 26 of the disc 24 and the
22 adhesive layer of the disc 24 is applied concentrically to the
23 convex face of the plastic disc 16. To aid in this operation,
24 a pilot aperture 60 is provided at the center of the disc 16.

25 After heat and pressure is applied at the zone z, as was
26 previously described, at least one mounting disc 12 is placed on
27 a plastic sheet 54 (Fig. 4) which will form the proximal wall 56
28 of one or more ostomy pouches 14. Each disc 12 is placed over

1 an opening 62 (Fig. 2) in the sheet 54. The proximal surface of
2 the sheet 54 may be covered with a cloth-like porous material 58
3 for the comfort of the wearer. The pilot openings 52, 48, 46,
4 and 60 may be die-cut to form the properly sized stoma inlet
5 portal 38. Heat and pressure are again applied at the zone z to
6 seal the annular rim 20 to the sheet 54. After the sealing
7 operation, the sheet 54 is backed by another sheet 64 which will
8 form a distal wall 66 of one or more ostomy pouches 14. The
9 pouches 14 are then formed by die-cutting along a line 68 and
10 heat sealing along a peripheral band 70 (Fig. 1).

11 While the invention has been shown and described with
12 respect to particular embodiments thereof, those embodiments are
13 for the purpose of illustration rather than limitation, and other
14 variations and modifications of the specific embodiments herein
15 described will be apparent to those skilled in the art, all
16 within the intended spirit and scope of the invention. Accord-
17 ingly, the invention is not to be limited in scope and effect to
18 the specific embodiments herein described, nor in any other way
19 that is inconsistent with the extent to which the progress in the
20 art has been advanced by the invention.